



SPW 1635

DOCKET NO: C1039.70048US00

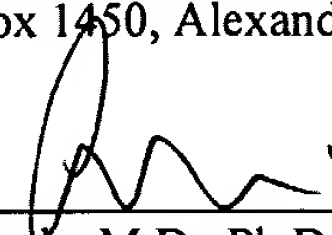
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Krieg et al.
Serial No: 09/818,918
Confirmation No: 4953
Filed: March 27, 2001
For: IMMUNOSTIMULATORY NUCLEIC ACID
MOLECULES

Examiner: Jane J. Zara
Art Unit: 1635

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 20th day of August, 2004.



Alan W. Steele, M.D., Ph.D., Reg. No. 45,128

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**SUPPLEMENTAL STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§ 1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. § 1.97

This Information Disclosure Statement has been filed before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114.

No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications (copies enclosed) that may contain subject matter related to this application:

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
C1041.70002US00	09/241,653	February 2, 1999	Wagner et al.
C1041.70005US00	09/355,254	February 22, 2000	Wagner et al.
C1039.70044US00	09/672,126	September 27, 2000	Hartmann et al.
C1041.70010US00	09/786,436	March 2, 2001	Wagner et al.
C1037.70042US00	10/613,524	July 3, 2003	Krieg
C1037.70044US00	10/613,736	July 3, 2003	Krieg
C1037.70049US00	10/643,141	August 18, 2003	Hutcherson et al.
C1037.70048US00	10/644,052	August 19, 2003	Jurk et al.
C1040.70012US00	10/644,267	August 20, 2003	Davis et al.
C1039.70084US00	10/649,584	August 25, 2003	Krieg et al.
C1041.70040US00	10/666,844	September 19, 2003	Lipford et al.
C1037.70052US00	10/668,050	September 22, 2003	Bratzler et al.
C1039.70083US00	10/690,495	October 21, 2003	Krieg et al.
C1037.70038US01	10/735,592	December 11, 2003	Krieg et al.
C1039.70048US01 ¹	10/769,282	January 30, 2004	Krieg et al.
C1039.70083US01 ²	10/769,626	January 30, 2004	Krieg et al.
C1039.70083US02 ²	10/787,737	February 26, 2004	Krieg et al.
C1039.70083US04 ²	10/788,191	February 26, 2004	Krieg et al.
C1039.70083US03 ²	10/788,199	February 26, 2004	Krieg et al.
C1039.70083US06 ²	10/789,051	February 26, 2004	Krieg et al.
C1039.70083US07 ²	10/789,353	February 26, 2004	Krieg et al.
C1039.70083US05 ²	10/789,536	February 26, 2004	Krieg et al.
C1041.70005US01 ³	10/811,226	March 26, 2004	Wagner et al.
C1037.70039US01	10/816,220	April 1, 2004	McCluskie et al.
C1039.70048US02 ¹	10/817,165	April 2, 2004	Krieg et al.
C1039.70048US03 ¹	10/831,647	April 23, 2004	Krieg et al.
C1039.70058US01	10/831,775	April 23, 2004	Davis et al.
C1037.70013US01	10/831,778	April 23, 2004	Bratzler et al.

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
C1039.70057US01	10/838,659	May 3, 2004	Davis et al.
C1039.70048US04 ¹	10/847,642	May 15, 2004	Krieg et al.
C1039.70083US08 ²	10/847,650	May 15, 2004	Krieg et al.
C1041.70036US01	10/872,196	June 18, 2004	Lipford et al.
C1041.70002US03 ⁴	10/876,892	June 25, 2004	Wagner et al.
C1041.70002US02 ⁴	10/876,965	June 25, 2004	Wagner et al.
C1041.70002US01 ⁴	10/877,369	June 25, 2004	Wagner et al.
C1039.70048US05 ¹	10/877,407	June 24, 2004	Krieg et al.
C1041.70016US01	10/884,372	July 2, 2004	Bauer et al.
C1039.70048US06 ¹	10/884,852	July 2, 2004	Krieg et al.
C1039.70035US01 ⁵	10/884,866	July 2, 2004	Krieg et al.
C1039.70083US10 ²	10/888,089	July 9, 2004	Krieg et al.
C1039.70048US08 ¹	10/888,449	July 9, 2004	Krieg et al.
C1039.70048US07 ¹	10/888,785	July 9, 2004	Krieg et al.
C1039.70035US02 ⁵	10/888,803	July 9, 2004	Krieg et al.
C1039.70083US09 ²	10/888,885	July 9, 2004	Krieg et al.
C1040.70006US01 ⁶	10/888,886	July 9, 2004	McCluskie et al.
C1041.70005US02 ³	10/894,655	July 16, 2004	Wagner et al.
C1039.70048US09 ¹	10/894,657	July 16, 2004	Krieg et al.
C1039.70048US10 ¹	10/894,862	July 16, 2004	Krieg et al.
C1041.70024WO00	PCT/US04/12788	April 22, 2004	Vollmer et al.

¹Copy not enclosed; identical specification as instant application 09/818,918

²Copy not enclosed; see C1039.70083US00, Serial No. 10/690,495 for identical specification

³Copy not enclosed; see C1041.70005US00, Serial No. 09/355,254 for identical specification

⁴Copy not enclosed; see C1041.70002US00, Serial No. 09/241,653 for identical specification

⁵Copy not enclosed; see previously cited C1039.70035US00, Serial No. 09/699,187 for identical specification

⁶Copy not enclosed; see previously cited C1040.70006US00, Serial No. 09/316,199 for identical specification

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;

2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;

3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. § 102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,
Krieg et al., *Applicant*

By: 

Alan W. Steele, M.D., Ph.D., Reg. No. 45,128
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600 Atlantic Avenue
Boston, Massachusetts 02210-2211
Telephone: (617) 646-8000

Docket No. C1039.70048US00
Date: August 20, 2004
XNDDX



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Alan W. Steele, M.D., Ph.D., Reg. No. 45,128

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Alexandria, VA 22313-1450

TRANSMITTAL

Sir:

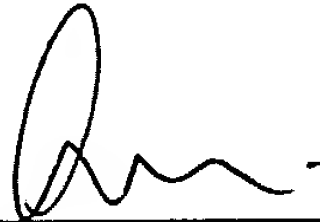
Transmitted herewith are the following documents:

- ☒ Supplemental Statement Filed Pursuant to the Duty of Disclosure Under 37 CFR §§1.56, 1.97 and 1.98
- ☒ PTO-1449 Form and references (2 boxes sent)
- ☒ Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

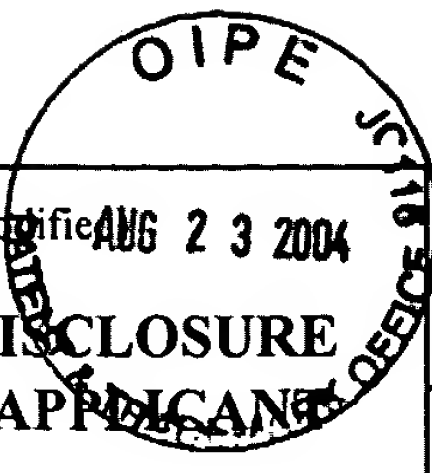
No check is enclosed. If a fee is required, please charge to Deposit Account 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,
Krieg et al., *Applicant*

By: 

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XNDDX



FORM PTO-1449/A and B (Modified)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

APPLICATION NO.: 09/818,918

ATTY. DOCKET NO.: C1039.70048US00

FILING DATE: March 27, 2001

CONFIRMATION NO.: 4953

APPLICANT: Krieg et al.

GROUP ART UNIT: 1635

EXAMINER: Jane J. Zara

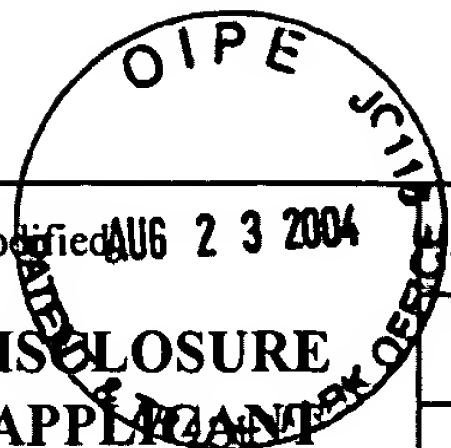
Sheet 1 of 3

U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A27	6,086,898	B1	DeKruyff et al.	07-11-2000
	A28	2002/0064515	A1	Krieg et al.	05-30-2002
	A29	2003/0026782	A1	Krieg et al.	02-06-2003
	A30	2003/0050261	A1	Krieg et al.	03-13-2003
	A31	2003/0050268	A1	Krieg et al.	03-13-2003
	A32	2003/0087848	A1	Bratzler et al.	05-08-2003
	A33	6,653,292	B1	Krieg et al.	11-05-2003
	A34	2003/0232074	A1	Lipford et al.	12-18-2003
	A35	2004/0009949	A1	Krieg	01-15-2004
	A36	2004/0030118	A1	Wagner et al.	02-12-2004
	A37	2004/0053880	A1	Krieg	03-18-2004
	A38	2004/0067905	A1	Krieg	04-08-2004
	A39	6,727,230	B1	Hutcherson et al.	04-27-2004
	A40	2004/0087534	A1	Krieg et al.	05-06-2004
	A41	2004/0087538	A1	Krieg et al.	05-06-2004
	A42	2004/0092472	A1	Krieg	05-13-2004
	A43	2004/0131628	A1	Bratzler et al.	07-08-2004
	A44	2004/0132685	A1	Krieg et al.	07-08-2004

FOREIGN PATENT DOCUMENTS

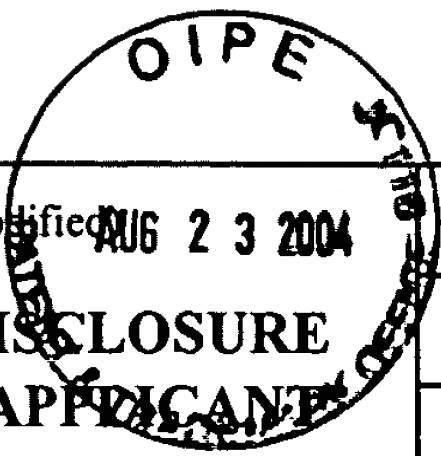
Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
	B9	WO	98/18810	A1		05-07-1998	
	B10	WO	98/37919	A1		09-03-1998	
	B11	WO	98/40100	A1		09-17-1998	
	B12	WO	98/52581	A1		11-26-1998	
	B13	WO	99/51259	A2		10-14-1999	
	B14	WO	99/61056	A2		12-02-1999	
	B15	WO	00/54803	A2		09-21-2000	
	B16	WO	01/22972	A2		04-05-2001	
	B17	WO	01/95935	A1		12-20-2001	
	B18	WO	01/97843	A2		12-27-2001	
	B19	WO	02/22809	A2		03-21-2002	
	B20	WO	02/053141	A2		07-11-2002	
	B21	WO	03/012061	A2		02-13-2003	
	B22	WO	03/015711	A2		02-27-2003	
	B23	WO	03/031573	A2		04-17-2003	
	B24	WO	03/103586	A2		12-18-2003	
	B25	WO	2004/007743	A2		01-22-2004	



FORM PTO-1449/A and B (Modified)		APPLICATION NO.: 09/818,918	ATTY. DOCKET NO.: C1039.70048US00
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		FILING DATE: March 27, 2001	CONFIRMATION NO.: 4953
		APPLICANT: Krieg et al.	
		GROUP ART UNIT: 1635	EXAMINER: Jane J. Zara
Sheet	2	of	3

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C20	ABED et al., Interferon-gamma regulation of B lymphocyte differentiation: activation of B cells is a prerequisite for IFN-gamma-mediated inhibition of B cell differentiation. Cell Immunol. 1994 Feb;153(2):356-66.	
	C21	AGRAWAL et al., Pharmacokinetics, biodistribution, and stability of oligodeoxynucleotide phosphorothioates in mice. Proc Natl Acad Sci U S A. 1991 Sep 1;88(17):7595-9.	
	C22	Allergen Nomenclature, List of allergens (as of March 12, 2004).	
	C23	CARSON et al., Oligonucleotide adjuvants for T helper 1 (Th1)-specific vaccination. J Exp Med. 1997 Nov 17;186(10):1621-2.	
	C24	DUNN et al., The three Es of cancer immunoediting. Annu Rev Immunol. 2004;22:329-60. Review.	
	C25	DURHAM et al., Immunotherapy and allergic inflammation. Clin Exp Allergy. 1991 Jan;21 Suppl 1:206-10.	
	C26	FRANCOIS et al., Examination of the inhibitory and stimulatory effects of IFN-alpha, -beta, and -gamma on human B-cell proliferation induced by various B-cell mitogens. Clin Immunol Immunopathol. 1988 Sep;48(3):297-306.	
	C27	FRISSORA et al., IFN-gamma-mediated inhibition of antigen receptor-induced B cell proliferation and CREB-1 binding activity requires STAT-1 transcription factor. Eur J Immunol. 2003 Apr;33(4):907-12.	
	C28	JILEK et al., Antigen-independent suppression of the allergic immune response to bee venom phospholipase A(2) by DNA vaccination in CBA/J mice. J Immunol. 2001 Mar 1;166(5):3612-21.	
	C29	KUBY et al., Editors, "Chapter 13: Cytokines", Immunology: Second Edition, W.H. Freeman and Company, New York. 1994. p297-322.	
	C30	LIEBSON et al., Role of gamma-interferon in antibody-producing responses. Nature. 1984 Jun 28-Jul 4;309(5971):799-801.	
	C31	LOTZ et al., Effects of recombinant human interferons on rheumatoid arthritis B lymphocytes activated by Epstein-Barr virus. J Rheumatol. 1987 Feb;14(1):42-5.	
	C32	MA et al., DNA-based vaccination against hepatitis C virus (HCV): effect of expressing different forms of HCV E2 protein and use of CpG-optimized vectors in mice. Vaccine. 2002 Sep 10;20(27-28):3263-71.	
	C33	MARDH et al., Alternaria alternata as a cause of opportunistic fungal infections in man. Scand J Infect Dis Suppl. 1978;(16):36-40.	
	C34	METZGER et al., Enhancement of humoral immunity by interleukin-12. Ann N Y Acad Sci. 1996 Oct 31;795:100-15.	
	C35	MOND et al., Recombinant interferon-gamma inhibits the B cell proliferative response stimulated by soluble but not by Sepharose-bound anti-immunoglobulin antibody. J Immunol. 1985 Oct;135(4):2513-7.	
	C36	PISETSKY et al., Mechanisms of autoantibody production in autoimmune MRL mice. J Exp Med. 1980 Nov 1;152(5):1302-10.	
	C37	RAZ et al., Preferential induction of a Th1 immune response and inhibition of specific IgE antibody formation by plasmid DNA immunization. Proc Natl Acad Sci U S A. 1996 May 14;93(10):5141-5.	
	C38	REYNOLDS et al., Inhibition of B lymphocyte activation by interferon-gamma. J Immunol. 1987 Aug 1;139(3):767-73.	
	C39	SIDMAN et al., Gamma-interferon is one of several direct B cell-maturing lymphokines. Nature. 1984 Jun 28-Jul 4;309(5971):801-4.	
	C40	STEIN et al., Antisense oligonucleotides as therapeutic agents--is the bullet really magical? Science. 1993 Aug 20;261(5124):1004-12. Review.	
	C41	WALLNER et al., Immunotherapy with T-cell-reactive peptides derived from allergens. Allergy. 1994 May;49(5):302-8.	



FORM PTO-1449/A and B (Modified)		APPLICATION NO.: 09/818,918	ATTY. DOCKET NO.: C1039.70048US00
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		FILING DATE: March 27, 2001	CONFIRMATION NO.: 4953
		APPLICANT: Krieg et al.	
		GROUP ART UNIT: 1635	EXAMINER: Jane J. Zara
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	C42	WEERATNA et al., Optimization strategies for DNA vaccines. Intervirology. 2000;43(4-6):218-26.		
	C43	WHALEN et al., DNA-mediated immunization to the hepatitis B surface antigen. Activation and entrainment of the immune response. Ann N Y Acad Sci. 1995 Nov 27;772:64-76.		
	C44	ZHANG et al., Antigen- and isotype-specific immune responses to a recombinant antigen-allergen chimeric (RAAC) protein. J Immunol. 1993 Jul 15;151(2):791-9.		

EXAMINER	DATE CONSIDERED
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. __, filed __, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE - The Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC 371 after June 30, 2003. See 37 CFR 1.491(b). For all patent applications filed on or before June 30, 2003, copies of cited U.S. patents and patent application publications are still required unless an eIDS is filed. Copies of all other patent(s), publication(s), or other information listed must still be provided, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]